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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,061	WANGH, LAWRENCE J.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 87-97 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 87-97 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10 March 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/10/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 87-97 are pending.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,480,772. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to claims 1-5 of '772.

Claims 87-96 are drawn to methods for reprogramming a non-human animal somatic cell comprising activating the somatic cell nucleus, preparing an egg recipient and transplanting the somatic cell nucleus into the recipient egg to yield a transplanted nucleus, where said transplanted nucleus is reprogrammed to direct development of an embryo. Claims 1-5 of '772 are drawn to in vitro activation of human fetal red blood cell nucleus or a

fetal cell found in amniotic fluid comprising isolating the nucleus from the cell and pretreating the nucleus with a non-ionic detergent, contacting the nucleus with CSF cytoplasm and with activating egg cytoplasm. The present claims are obvious over those of '722 because human fetal blood cells and cells found in amniotic fluid are somatic cells, and these cells are defined in the present specification as useful in the presently claimed method. Further each claim limitation in '722 can be found in the present specification, and thus is defined by "comprising" the present claims. Thus at the time of the present invention, it would have been obvious to the ordinary artisan to make the invention of present claims 87-96 given claims 1-5 of '722. Applicant is reminded that the preamble does not alter the obviousness when the method steps are the same or when the method claims are generic to the allowed claims.

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,651,992. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to claims 1-14 of '992.

Claims 87-96 are drawn to methods for reprogramming a non-human animal somatic cell comprising activating the somatic cell nucleus, preparing an egg recipient and transplanting the somatic cell nucleus into the recipient egg to yield a transplanted nucleus, where said transplanted nucleus is reprogrammed to direct development of an embryo.

Claims 1-14 are drawn to a method for in vitro activation of a nucleus from a human fetal cell comprising separating the nucleus from the cell and contacting the nucleus with an activating egg extract. Fetal cells, as well as the specific cells claimed in claims 2 and 3, are all somatic cells as presently claimed, and are defined by the specification as claimed to be used in the invention of claims 87-96. Further, the use of a detergent, the specific detergent, activating under conditions where the cells do not synthesize nucleic acids as well as the activating egg extract being from Xenopus eggs are all contained in the present specification as definitions of the claimed invention. Thus, at the time of the present invention, it would have been obvious to the ordinary artisan to make the invention of present claims 87-96 given the claims 1-14 of '992. Applicant is reminded that the preamble does not alter the obviousness when the method steps are the same or when the method claims are generic to the allowed claims.

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 5,773,217. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to claims 1-14 of '217.

Claims 87-96 are drawn to methods for reprogramming a non-human animal somatic cell comprising activating the somatic cell nucleus, preparing an egg recipient and transplanting the somatic cell nucleus into the recipient egg to yield a transplanted nucleus,

where said transplanted nucleus is reprogrammed to direct development of an embryo. Claims 1-29 of '217 are drawn to methods of activating sperm cells. Since sperm cells are non-dividing cells, the present claims are generic to claims 1-29 of '217. Each of the limitations found in claims 1-29 of '217 are defined in the present specification as elements to be used in the present claims given the use of "comprising." Thus, at the time of the present invention, it would have been obvious to the ordinary artisan to make the invention of present claims 87-96 given claims 1-29 of '217. Applicant is reminded that the preamble does not alter the obviousness when the method steps are the same or when the method claims are generic to the allowed claims.

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,753,457. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to claims 1-6 of '457.

Claims 87-96 are drawn to methods for reprogramming a non-human animal somatic cell comprising activating the somatic cell nucleus, preparing an egg recipient and transplanting the somatic cell nucleus into the recipient egg to yield a transplanted nucleus, where said transplanted nucleus is reprogrammed to direct development of an embryo. Claims 1-6 of '457 are drawn to a method for reprogramming a non-dividing nucleus, comprising contacting said nucleus with a cytostatic factor-containing cytoplasmic extract of

a cell in meiotic metaphase II and contacting said nucleus with an activating egg cytoplasmic extract, and a method for reprogramming a somatic cell nucleus for transplantation into an egg. Somatic can be are non-dividing cells in an adult animal. Each of the limitations found in claims 1-6 of '457 are defined in the present specification as elements to be used in the present claims given the use of "comprising." Thus, at the time of the present invention, it would have been obvious to the ordinary artisan to make the invention of present claims 87-96 given claims 1-6 of '457.

Claims 87-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/969,646. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to claims 1-8 of '646.

Claims 87-96 are drawn to methods for reprogramming a non-human animal somatic cell comprising activating the somatic cell nucleus, preparing an egg recipient and transplanting the somatic cell nucleus into the recipient egg to yield a transplanted nucleus, where said transplanted nucleus is reprogrammed to direct development of an embryo. Claims 1-8 of '646 are drawn to a method of cloning a nonhuman mammal comprising incubating a permeablized cell in a reprogramming extract under conditions that allow the elimination of a factor from said nucleus or the addition of a factor from said extract, transplanting the reprogrammed nucleus into a nucleated or enucleated egg and allowing

the egg to develop into said nonhuman mammal. Each of the limitations found in claims 1-6 of '457 are defined in the present specification as elements to be used in the present claims given the use of "comprising." Thus, at the time of the present invention, it would have been obvious to the ordinary artisan to make the invention of present claims 87-96 given claims 1-6 of '457.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 87-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reprogramming an non human animal somatic cell isolated nucleus or a method reprogramming a nucleus of a somatic cells comprising releasing the nucleus from surrounding cytoskeleton comprising permeablizing the nucleus, incubating the nucleus with cytoplasm of an metaphase II oocyte, where the oocyte is from the same species as the nucleus, and incubating the nucleus with an activating egg cytoplasm, where the egg is from the same species as the nucleus, wherein said nucleus undergoes swelling, nucleic acid replication and entry into mitosis, does not reasonably provide enablement for any cell or any stage of the cell cycle, where the nucleus, the cytoplasms and recipient egg are of different species, and activation without incubation with activating egg cytoplasm, or development of an embryo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claims 87-97, the end result of the method, nuclear swelling, nucleic acid replication and entry into mitosis are events associated with activation (specification, at least at, page 3. lines 20-25 and page 5, lines 29-32). At the time of filing, reprogramming could only be assayed by the development of cloned animal. The mechanism of reprogramming was not known and frequently reprogramming wasn't complete as nuclear transfer embryos did not always develop to term (Kono, page 76, col. 2, parag. 2, lines 12-14 and page 77, col. 2, parag. 1, lines 3-5). Morphological events or structural changes observed associated with reprogramming were not clearly known but were though to include timing of cleavage, compaction and blastocoel formation and cell surface antigens (Kono, page 76, col. 2, parag. 2, lines 8-11 and parag. 3, lines 1 to page 77, line 1). Further, incubation of the nucleus in the presence of activating egg cytoplasm is critical to the activation method as activation is required to obtain nuclear swelling, nucleic acid replication and entry into mitosis. It appears that for the crucial elements of the CSF cytoplasm and the activating egg cytoplasm to enter the nucleus, the nucleus must first be permeablized, as the specification does not teach that the claimed method results in nuclear envelop breakdown, a requirement for exposure of the donor nuclei to MPF (Kono, page 76, col. 2, parag. 2, lines 1-5). Critical steps must be included for enablement.

The specification only teaches one type of cell, an MII oocyte, which has the capability of reprogramming the nucleus. For successful reprogramming, the art taught at the time of filing that the donor nucleus, in a nuclear transfer method needs to be exposed to MII cytoplasm (Kono, page 76, col. 2, parag. 2, lines 1-5 and Fluka, page 849, col. 2, parag. 3, lines 4-8). MFP is the active agent in the MII cytoplasm that contributes to reprogramming. While, reprogramming has not been clearly shown in the present case, the purpose of the incubation steps is for reprogramming. Thus, as the MII oocyte is the only cell known to contain sufficient levels of MFP to contribute to reprogramming, and the

specification discloses no other cells containing sufficient MFP to reprogram, the claims are enabled only for MII oocyte cytoplasm. Further, it is not clear if the CSF or activating egg cytoplasm from species different from that of the nucleus will provide sufficient MFP and other factors to give successful reprogramming and activation. It is known that with the more traditional nuclear transfer methods where donor nuclei were transferred into oocytes of a different species than the donor nuclei, the development of term-cloned animals is unpredictable (Dinnyes, page 82, col. 2, lines 8-10 and lines 15-20). Thus, the development of an embryo as stated in claim 87 is not enabled without further evidence.

Claim 97 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 97 is to a method for cloning a non-human animal from a somatic cell nucleus. However, at the time of filing the art recognized that nuclear transfer or cloning to produce a term animal was unpredictable. Even if applicant's method results in a reprogrammed somatic cell nucleus, it is documented in the arena of nuclear transfer/cloning that pregnancy does not necessarily mean live births. Tiger clones were lost well after pregnancy was established, as were domestic cats and rabbits. *Korean Now* (May 31, 2003) reports that a tiger became pregnant with a cloned tiger embryo made using a cow embryo, but that the tiger had a miscarriage. *The Wall Street Journal* (March 19, 2002) reports that an effort to clone a Siberian tiger but that cloning attempts have failed, although a tiger embryo was produced by nuclear transfer using a bovine oocyte. Robert Wall of the USDA is quoted as stating that despite years of effort, "[w]e're in the same bind that we've always been in. A majority of [would be clones] do not make it to term." (Pennisi, page 1722, col. 1, parag. 2, lines 9-14). Pennisi and Vogel state, "even when an embryo does successfully

implant in the womb, pregnancies often end in miscarriages" (Pennisi, page 1722, col. 1, parag. 3, lines 16-18). The case with rabbits indicates that obtaining an embryo by nuclear transfer does not translate into a cloned rabbit. While many cloned rabbit embryos can be made, they abort upon transfer to surrogate mothers, and in 2000, there had not been any successes in cloning rabbits (Pennisi, page 1725, col. 2, parag. 3). With primates, two cloned monkeys were produced, but there have been no subsequent successes in primate cloning (Pennisi, page 1726, col. 2, line 6 to col. 3, line 3). With regard to cats, one cloned cat has been produced, but given the difficulty in the art to produce a cloned cat and the lack of producibility as stated above, the cloning of cats is unpredictable. Two attempts to implant cat eggs or reconstructed embryos failed, providing for an unpredictable outcome for cat cloning (Pennisi, page 1726, col. 2, parag. 3, lines 4-5). Others have reported establishing pregnancies but no report of a cloned cat being born (Pennisi, page 1726, col. 2, parag. 3, lines 5-9 and 11-12). As the authors state, establishing pregnancies is only part of the problem and is not a guarantee of a cloned mammal being produced (Pennisi, page 1726, col. 2, lines 9-11). Given the recognized the low birth rate in nuclear transfer procedures, which applicant states their invention overcomes, an inability to carry to term is a significant issue. Given that the claimed method denatures the chromatin, this denaturation could have caused damage to chromosomes or genes needed for fetal development but not embryonic growth and implantation. Also see above, reference to Dinnyes. No embryonic development has been enabled. The evidence of record does not make clear that live births occurred as a result of the claimed method.

At the time of filing, cross-species nuclear transfer and the cloning of primates was not enabled at the time of filing. Meirelles demonstrates that methods of nuclear transfer where the nuclear material of *Bos indicus* is inserted into the oocyte of *Bos taurus* produces calves comprising the nuclear material of *Bos indicus* and the mitochondria of *Bos taurus*. Meirelles *et al.* teach that previous attempts to use the *Bos* oocyte as hosts for nuclear transfer from unrelated species allowed

development to the blastocyst stage, and conclude that incompatibility among the nuclear and mitochondrial genetic systems is responsible for the early arrest. Meirelles also points to similar failures using *Mus caroli* and *Mus musculus* citing Dominko. Meirelles conclude stat in light of their results and the failures of the prior art, that nuclear transfer across subspecies barriers is possible. (see Meirelles, pp. 351-355). In addition, the claims encompass methods of nuclear transfer when the oocyte is off a different species than the surrogate mother animal. Further, in the production of sheep goat chimeras, there were biases towards chimeras whose genotype and phenotype was most like that of the recipient, and that the successful production of chimeras resided in the neutralization of incompatibility between the chimeric embryo (Fehilly et al (1985), page 221, parag. 1). It is also noted the cloning of monkeys, a primate, by nuclear transfer had been successful when embryonic cells were the nuclear donor, not when somatic cells were used as nuclear donor (Mitalipov, abstract). Mitalipov further states, clearly, that somatic cell cloning, as is part of the present methods, has not been accomplished in primates (Mitalipov, page 1367, col. 2, parag, 3, lines 1-3). Simerly, states that in rhesus monkey NT units, DNA and microtubule imaging showed disarrayed mitotic spindles with misaligned chromosomes, which resulted in unequal chromosome segregation and aneuploid embryos (page 297, col. 2, parag. 1, lines 5-11). Therefore claim 97 would not be enabled for their present breadth.

Claim 97 also lacks enablement as the only means known in the art to produce a new organism is by transferring the nuclear transfer embryo into the uterus of a female. An animal will not develop otherwise.

Therefore the skilled artisan would need to engage in a due amount of experiment without a predictable degree of success to implement the invention as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 97 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 97 is to a cloning a nonhuman animal, but the body of the claims states "organism." This a broader scope than animal.

The claims are free of the prior art. At the time of filing, the prior art did not teach or suggest methods of nuclear transfer, where the donor nucleus was incubated first in a cytostatic egg extract and second in an activating egg extract.

The claims are free of the prior art. At the time of filing, the prior art did not teach or suggest methods of nuclear transfer, where the donor nucleus was incubated first in a cytostatic egg extract and second in an activating egg extract.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

March 19, 2006